MAY 1 9 2004

K033688

Micro H_2 Breath Monitoring Device with Hydra Software Utility
510(k) Summary

Submitter's Information:	Micro Medical Ltd. PO Box 6 Rochester Kent, ME1 2AZ United Kingdom
Contact Information **(US Representative for Micro Medical Ltd):**	Micro Direct, Inc. Mr. David Staszak 803 Webster Street Lewiston, Maine 04240
Telephone Number:	207-786-7808
Fax Number:	207-786-7280
Trade Name:	Micro H_2 Breath Monitoring Device with HYDRA Software Utility
Common Name:	Analyzer, Hydrogen Gas
Classification Name:	Xylose Test System
Regulation Number:	21 CFR 862.1820
Predicate Devices, 510(k) Numbers:	Micro H_2, K963376 HBT Sleuth, N/A

Indications For Use:

The Micro H_2 is a hand held hydrogen monitor used in the screening and diagnosis of lactose malabsorption, a condition that produces increased hydrogen levels in the blood when unabsorbed lactose reacts with bacteria in the intestines. This increased level of hydrogen is expired and can be measured after ingestion of lactose following a period of fasting.

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Target Population: Adult, Child and Infant.

Device Description:

The Micro H_2 Breath Monitoring device is a battery operated hand held hydrogen breath monitor. Clinicians using this device have a patient expel their breath into an inlet port through a disposable mouthpiece adapter. The hydrogen concentration is then displayed in parts per million (ppm). The software utility, product name Hydra, will be supplied to purchasers of the breath hydrogen monitoring device. At the clinician's discretion, they can install Hydra on a Windows based PC. Thereafter, the handheld Micro H_2 device can be connected to the PC via a serial communications cable to acquire and log successive breath hydrogen measurements during a diagnostic procedure.

Comparative Summary Tables

Contained in the following table is a predicate-proposed comparative of the proposed Micro H_2 device with the Hydra Utility software, the predicate Micro H_2 device without the Hydra Utility software Utility, and the predicate Breathe E-Z Systems, Inc. HBT Sleuth™ :

PARAMETER	***PREDICATE*** **HBT Sleuth™**	***PREDICATE*** K9633765 **Micro H_2 device without Hydra**	***PROPOSED*** K033688 **Micro H_2 device with Hydra**
Breath Hydrogen Measurement	Expel Breath Into Handheld Device	Expel Breath Into Handheld Device	Same as Predicate Devices
Recording Date of Test, Clinician Name, Institution ID, Patient ID, DOB, Reported Symptoms	Manual Transcription (Pen & Paper or Generic Word Processing/Spreadsheet Application Program)	Manual Transcription (Pen & Paper or Generic Word Processing/Spreadsheet Application Program)	Pop-Up Menus Presented to User. Relevant Data Entered into Field Though Mouse Driven Program Interface
Plotting Breath Hydrogen Concentration as a Function of Time for Diagnostic Evaluation	Manual Plotting (Pen & Paper or Generic Word Processing/Spreadsheet Application Program)	Manual Plotting (Pen & Paper or Generic Word Processing/Spreadsheet Application Program)	Breath Hydrogen Concentration Automatically Plotted as a Function of Time and Graphically Displayed.
Breath Hydrogen	Manual Timing	Manual Timing	Automatic in Real

PARAMETER	***PREDICATE*** **HBT Sleuth™**	***PREDICATE*** K9633765 **Micro H_2 device without Hydra**	***PROPOSED*** K033688 **Micro H_2 device with Hydra**
Measurement Interval	with Wall Clock or Stop Watch	with Wall Clock or Stop Watch	Time Mode. Hydra Program Tracks Time and Prompts for Next Measurement.
Electronic Archival/Retrieving of Test Data	Only if Test Data is Manually Managed with Word Processing/Spread-sheet Application	Only if Test Data is Manually Managed with Word Processing/Spread-sheet Application	Fully Automatic within Hydra User Interface
Test Protocol	Manually Determined, Managed and Administered	Manually Determined, Managed and Administered.	Hydra Software Provided with Several Suggested Diagnostic Presets for Lactose Malabsorption Producing an Elevated Breath Hydrogen Concentration. Clinicians on a Per Patient Basis can Manually Modify Suggested Preset Test Protocol Variables. Included within Protocol Variables are Threshold Parameters that if Used, Resultant Diagnostic Data is Automatically Compared.
Report Generation and Communication	Manual Transcription (Pen & Paper or Generic Word Processing/Spread-sheet Application Program)	Manual Transcription (Pen & Paper or Generic Word Processing/Spread-sheet Application Program)	Automatic within Hydra User Interface. Depending Upon Diagnostic Presets, Measured Breath Hydrogen Data is Compared to Thresholds and Can be Flagged as a

PARAMETER	***PREDICATE*** **HBT Sleuth™**	***PREDICATE*** K9633765 **Micro H_2 device without Hydra**	***PROPOSED*** K033688 **Micro H_2 device with Hydra**
			Suggested Diagnostic Should this Feature of the Hydra Interface be Invoked.
Power Source	Single Alkaline 9 volt	Single Alkaline 9 volt PP3	Same as Micro H_2
Environmental:			
Storage temperature	Unknown	-20° to + 70°	Same as Micro H_2
Storage humidity	15% to 90% non-condensing	30% to 90% RH	Same as Micro H_2
Operating temperature	Unknown	15° to 30°	Same as Micro H_2
Operating humidity	15% to 90% non-condensing	30% to 90% RH continuous (0 - 99% intermittent)	Same as Micro H_2
Performance:			
Operating Principle	Electrochemical	Electrochemical	Same as Micro H_2
Type	Micro Fuel Cell	Micro fuel cell	Same as Micro H_2
Range	0 – 500 ppm	0 – 500 ppm	Same as Micro H_2
Resolution	Unknown	1 ppm	Same as Micro H_2
Accuracy	+/- 5%	+/- 10% or 2 ppm whichever is the greater	Same as Micro H_2
Display	3.5" by 0.5"	3 1/2 digit LCD	Same as Micro H_2
Operating Pressure	Unknown	Atmospheric+/- 10%	Same as Micro H_2
Pressure coefficient	Unknown	0.02% signal per mBar	Same as Micro H_2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 19 2004

Mr. David Staszak
Micro Direct, Inc.
803 Webster Street
Lewiston, ME 04240

Re: k033688
Trade/Device Name: Micro H2 Breath Monitoring Device with Hydra Software Utility
Regulation Number: 21 CFR 862.1820
Regulation Name: Xylose test system
Regulatory Class: Class I
Product Code: NRH
Dated: May 5, 2004
Received: May 6, 2004

Dear Mr. Staszak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033688

Device Name: Micro H2 Breath Monitoring Device with Hydra Software Utility

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Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

Target Population: Adult, Child and Infant.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K033688